For the reasons discussed in the preamble, the Consumer Product Safety Commission amends 16 CFR part 1512 as follows:

PART 1512—REQUIREMENTS FOR BICYCLES

§ 1512.6 Requirements for steering system.

(a) Handlebar stem insertion mark. Quill-type handlebar stems shall contain a permanent ring or mark which clearly indicates the minimum insertion depth of the handlebar stem into the fork assembly. The insertion mark shall not affect the structural integrity of the stem and shall not be less than 2 1/2 times the stem diameter from the lowest point of the stem. The stem strength shall be maintained for at least a length of one shaft diameter below the mark.

(b) Handlebar. Handlebars shall allow comfortable and safe control of the bicycle. Handlebar ends shall be symmetrically located with respect to the longitudinal axis of the bicycle and no more than 406 mm (16 in) above the seat surface when the seat is in its lowest position and the handlebar ends are in their highest position. This requirement does not apply to recumbent bicycles.

§ 1512.12 Requirements for wheel hubs.

(a) Quick-release devices. Lever-operated, quick-release devices shall be adjustable to allow setting the lever position for tightness. Quick-release levers shall be clearly visible to the rider and shall indicate whether the levers are in a locked or unlocked position. Quick-release clamp action shall embrace the frame or fork when locked, except on fiber reinforced plastics.

(b) Seat post. The seat post shall contain a permanent mark or ring that clearly indicates the minimum insertion depth (maximum seat-height adjustment); the mark shall not affect the structural integrity of the seat post. This mark shall be located no less than two seat-post diameters from the lowest point on the post shaft, and the post strength shall be maintained for at least a length of one shaft diameter below the mark. This requirement does not apply to bicycles with integrated seat masts, however, a permanent mark or other means to clearly indicate that the seat or seat posts is safely installed shall be provided.

7. Amend § 1512.18 by revising paragraphs (k)(1)(i) and (n)(2)(vii) as follows:

§ 1512.18 Tests and test procedures.

(a) Sidewalk bicycle means a bicycle with a seat height of no more than 635 mm (25.0 in); the seat height is measured with the seat adjusted to its lowest position and the handlebar ends are in their highest position. Recumbent bicycles are not included in this definition.

(b) Track bicycle means a bicycle designed and intended for sale as a competitive velodrome machine having no brake levers or calipers, single crank-to-wheel ratio, and no free-wheeling feature between the rear wheel and the crank.

(c) Recumbent bicycle means a bicycle in which the rider sits in a reclined position with the feet extended forward to the pedals.

§ 1512.4 Mechanical requirements.

(a) Sharp edges. There shall be no unfinished sheared metal edges or other sharp parts on assembled bicycles that are, or may be, exposed to hands or legs; sheared metal edges that are not rolled shall be finished so as to remove any feathering of edges, or any burrs or spurs caused during the shearing process.

(i) Control cable ends. Ends of all accessible control cables shall be provided with protective caps or otherwise treated to prevent unraveling. Protective caps shall be tested in accordance with the protective cap and end-mounted devices test, § 1512.18(c), and shall withstand a pull of 8.9 N (2.0 lbf).

4. Amend § 1512.6 by revising paragraphs (a) and (c) to read as follows:
SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Pfizer, Inc. The NADA provides for the veterinary prescription use of gonadotropin releasing factor-diphtheria toxoid conjugate by subcutaneous injection for temporary immunological castration (suppression of testicular function) and reduction of boar taint in intact male pigs intended for slaughter.

DATES: This rule is effective May 13, 2011.

FOR FURTHER INFORMATION CONTACT: Matthew Lucia, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8116, e-mail: matthew.lucia@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed NADA 141–322 that provides for the veterinary prescription use of IMPROVEST (gonadotropin releasing factor-diphtheria toxoid conjugate) Sterile Solution for Injection for temporary immunological castration (suppression of testicular function) and reduction of boar taint in intact male pigs intended for slaughter. The application is approved as of March 22, 2011, and the regulations are amended in 21 CFR part 522 to reflect approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.110(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

The Agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:


2. Add § 522.1083 to read as follows:

§ 522.1083 Gonadotropin releasing factor-diphtheria toxoid conjugate.

(a) Specifications. Each milliliter (mL) of solution contains 0.2 milligrams (mg) gonadotropin releasing factor-diphtheria toxoid conjugate.

(b) Sponsor. See No. 000069 in § 510.600(c) of this chapter.

(c) Conditions of use in swine—(1) Amount. Administer 0.4 mg per intact male pig (2 mL) by subcutaneous injection no earlier than 9 weeks of age. A second subcutaneous injection of 0.4 mg per intact male pig (2 mL) should be administered at least 4 weeks after the first dose. Pigs should be slaughtered no earlier than 4 weeks and no later than 8 weeks after the second dose.

(2) Indications for use. For the temporary immunological castration (suppression of testicular function) and reduction of boar taint in intact male pigs intended for slaughter.

(3) Limitations. Not approved for use in female pigs and barrows. Do not use in intact male pigs intended for breeding because of the disruption of reproductive function. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: May 4, 2011.

Bernadette Dunham,
Director, Center for Veterinary Medicine.

BILLING CODE 4160–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation’s regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in June 2011. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective June 1, 2011.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)


PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC’s historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for June 2011.1

The June 2011 interest assumptions under the benefit payments regulation will be 2.50 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit’s placement in pay status. In comparison with the interest

1 Appendix B to PBGC’s regulation on Allocation of Assets in Single-Employer Plans (29 CFR Part 4044) prescribes interest assumptions for valuing benefits under terminating covered single-employer plans for purposes of allocation of assets under ERISA section 4044. Those assumptions are updated quarterly.